Vaccine Adverse Event Reporting System

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VAERS

To contact the Vaccine Adverse Event Reporting System write:

VAERS
P.O. Box 1100
Rockville, MD 20849

Or call: 1-800-822-7967

To contact the National Vaccine Injury Compensation Program write:

NVICP
Parklawn Building, Room 8-05
56 Fishers Lane
Rockville, MD 20849

Or call: 1-800-338-2382

To access VAERS data through the National Technical Information Service write:

NTIS
5285 Port Royal Road
Springfield, VA 22161

Or call: (703) 487-4650

Note: The intervals or time periods from vaccine administration to manifestation of illness, disability, injury, or condition differ between the Vaccine Injury Table and the Reportable Events Table (RET). The documented time periods on the Vaccine Injury Table provide the time-frame for demonstration of clinical symptoms that are necessary to qualify for compensation. The documented intervals on the Reportable Events Table (RET) provide the time-frame for the required reporting of adverse events.

VACCINE ADVERSE EVENT REPORTING SYSTEM

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VAERS

Introduction to VAERS
Call 1-800-822-7967

What is VAERS?

The National Childhood Vaccine Injury Act (NCVIA) of 1986 created a unified system to help identify rare vaccine reactions. This system, initiated in 1990 and jointly managed by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), is called the Vaccine Adverse Event Reporting System (VAERS). VAERS receives reports of adverse events following vaccination from vaccine manufacturers, private practitioners, state and local public health clinics, and vaccinees themselves (or their parents or guardians). It is similar in intent and operation to surveillance systems for other types of pharmaceutical products, such as the MedWatch system maintained by the FDA, and to safety surveillance programs in other countries. Such systems are essential to the discovery of potential rare adverse consequences of pharmaceutical products that may not become evident until millions of people have been exposed to these products. But these surveillance systems have important limitations that complicate the interpretation of the data they accumulate.

How VAERS works.

VAERS is a passive surveillance system, a repository for voluntarily submitted reports. (An active surveillance system, in contrast, would follow all individuals in a defined population to determine their responses to vaccination.) To encourage reporting of any possibly vaccine-induced adverse event, the criteria for reporting to VAERS are unrestrictive; the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem. The NCVIA requires physicians to report--directly to VAERS or to the manufacturer--certain categories of serious outcomes occurring within a short period of time following specified childhood vaccinations; thus one might expect a fairly complete reporting of such events. However, the lack of enforcement provisions or even any monitoring of reporting practices precludes any assumptions about the extent to which such events are in fact reported. Thus, VAERS potentially suffers both from underreporting--not all vaccine-induced events are reported--and overreporting--coincidental events, not caused by vaccines, can be reported.

Approximately 10,000 reports per year are submitted to VAERS. About 15% of these describe a serious event, defined for regulatory purposes as an event resulting in death, life-threatening illness, hospitalization, prolongation of existing hospitalization, or permanent disability. These reports are entered into the system by a Federal contractor and are reviewed by medical staff of the FDA's Center for Biologics Evaluation and Research and CDC. Most of the approximately 85% of reports not classified as serious describe events such as local reactions and fever occurring within a day or two of vaccination. Many of these events are clearly caused by the vaccine. The serious events, unfortunately, are much more difficult to evaluate with regard to their causal association with vaccines. Most of these tend to be of a type known to occur in the absence of vaccines as well, so in an individual case it is almost never possible to definitively assess the role of the vaccine.

Temporal versus causal associations.

Because of the large number of vaccine exposures, it is clear that temporal associations with

adverse outcomes will occur even when there is no true causal association. With hepatitis B vaccine now recommended for all new borns and other childhood vaccines (DTP, OPV, Hib) being administered to nearly all infants starting at two months of age, most health problems in infancy (of which there are many), whatever their cause, will occur in children who have been vaccinated. Some of these problems will by chance occur in recently vaccinated children.

Strengths and weaknesses of VAERS.

As a database for epidemiologic studies, VAERS has many weaknesses. One major problem is that since unvaccinated people experiencing adverse events are not reported to VAERS, there is no control group to study. Thus, there is no way to assess whether the number of reported events is different from the number that would have been observed in the absence of vaccination.

The quality of the data is also less than optimal. Because reports are sent in by a wide variety of individuals, few of whom are experienced in completing data forms for medical studies, many reports omit important data and contain obvious errors. Given that VAERS receives over 10,000 reports annually, it is difficult to assure the accuracy and completeness of the database with current resources, although checks and follow-up are performed for a few key data items such as the type of vaccine administered and the severity of the event.

Finally, the administration of multiple vaccines at the same time, following currently recommended vaccine schedules, further complicates the assessment of adverse outcomes because there is usually no way to determine which of the vaccines (if any) was most likely to cause the outcome.

This is not to diminish the value of such a system. While VAERS data can rarely provide definitive evidence of causal associations between vaccines and particular reported outcomes, this type of national reporting system can rapidly document possible effects, generating early warning signals that can then be more rigorously investigated in focused studies. In a sense, VAERS is the “front line” of vaccine safety surveillance, so sensitivity takes precedence over specificity; reporting of all serious events following vaccination is encouraged, inevitably resulting in large numbers of reports that do not represent vaccine-induced problems. VAERS data are especially valuable in assessing the safety of newly marketed vaccines. Careful review of reports coming in during the initial months of availability can provide additional reassurance about the safety of the vaccine or rapidly identify potential problems not observed during the investigational phase.

Who can report to VAERS?

Anyone can report to VAERS. VAERS reports are usually submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Patients, parents, and guardians are encouraged to seek the help of a health-care professional in reporting to VAERS.

Why should I report to VAERS?

Registries of disease or injury work best when reporting is complete. Complete reporting of post-vaccination events supplies public health professionals with the information they need to ensure the safest strategies of vaccine administration.

Does my reporting injuries (or deaths) to VAERS affect personal liability?

No. The National Childhood Vaccine Injury Act of 1986 provides liability protection through the Vaccine Injury Compensation Program. In light of this protection, practitioner liability is unaffected by the VAERS reporting requirement.

What events should be reported to VAERS?

Although NCVIA only requires reporting of the post-vaccination adverse events mentioned in the **Reportable Events Table**, VAERS encourages all reporting of any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States.

The **Reportable Events Table** specifically outlines the reportable post-vaccination events and the time frames in which they must occur in order to qualify as being reportable. A copy of the Table can be obtained by calling 1-800-822-7969.

The NCVAIA requires the following events be reported:
1) Any event set forth in the *Reportable Events Table* that occurs within the time period specified.
2) Any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine.

How can I get rapid information on VAERS, such as how to file a report?

There is a toll-free VAERS information line that is currently receiving over 1600 calls per month. The calls come from a variety of sources. Many calls are to obtain copies of VAERS forms or to receive assistance from a VAERS staff member in filling out the VAERS form. Other services include general information on VAERS, information about vaccines from a health care professional, and mailed copies of the **Reportable Events Table**.

A VAERS report form has been designed to facilitate and standardize the process of reporting adverse events following vaccination to VAERS. The report form consists of a single page, pre-addressed, postage-paid form for entering pertinent information, including a narrative description of the adverse event.

Report forms can be obtained at www.fda.gov/cber/vaers/vaers.htm or by calling VAERS at 1-800-822-7969. Xerox copies may also be used.

Are VAERS data available to the public?

Yes. Once any identifying information is removed, VAERS data are made available to the public, for a fee, through the National Technical Information Service (NTIS).

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (NVICP) is a Federal "no-fault" system for resolving claims concerning possible reactions to mandated childhood vaccines.

Reference: Atkinson, W., Furphy, L., Humiston, S., Pollard, B., Nelson, R., Wofle, C. (ed.), September 1997. Epidemiology and Prevention of Vaccine-Preventable Diseases. 4th ed. Centers for Disease Control and Prevention, Atlanta, GA.

Reference: Ellenberg, S., Chen, R. Journal of the U.S. Public Health Service, *Public Health Reports*, January/February, 1997 (Vol 112, No. 1; pp. 10-20).